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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/688,648 | 10/17/2003 | Tero Ahola | PC25479A | 1230 |

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| EXAMINER | |
|---|---|
| SOROUSH, LAYLA | |
| ART UNIT | PAPER NUMBER |
| 1617 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 01/09/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/688,648 | AHOLA, TERO | |
| | Examiner | Art Unit | |
| | Layla Soroush | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10/17/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/02/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The Office Action is in response to the Preliminary amendment filed October 17, 2003. Claims 1-36 are pending.

### *Claim Rejections - 35 USC § 112*

Claims 1-36 is rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for treatment of hepatitis c virus (infections) using all prenylation inhibitors, cholesterol biosythensis inhibitors, or inhibitors of HMG-CoA reductase. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. While the specification is enabled for the treatment of hepatits c virus using the prenylation inhibitor, cholesterol biosythensis inhibitor, and inhibitor of HMG-CoA reductase, atorvastin, it does not provide sufficient information that all prenylation inhibitors, cholesterol biosythensis inhibitors, or inhibitors of HMG-CoA reductase, will treat hepatits c virus (infections). The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention', (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims', (6) the amount of direction or guidance presented', (7) the presence or absence of working examples', and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1). The Nature of the Invention: Claims 1-36 are drawn to an invention which pertains to a method treating hepatitis C infection comprising the step of administering to a subject in need thereof an effective amount of a prenylation inhibitor, cholesterol biosythensis inhibitor, or inhibitor of HMG-CoA reductase or a pharmaceutically acceptable salt thereof.

(2). The state of the prior art: The state of the art on prenylation inhibitors, cholesterol biosythensis inhibitors, or inhibitors of HMG-CoA reductase is relatively high.

(3). The predictability or unpredictability of the art: The specification fails to enable one of ordinary skill in the art to practice the presently claimed method for treatment of hepatitis c virus (infections) using all prenylation inhibitors, cholesterol biosythensis inhibitors, or inhibitors of HMG-CoA reductase. Thus, the state of the art is unpredictable.

(4). The breadth of the claims: The claims encompass a method of treating hepatitis C infection comprising the step of administering to a subject in need thereof an effective amount of a prenylation inhibitor, cholesterol biosythensis inhibitor, or inhibitor of HMG-CoA reductase or a pharmaceutically acceptable salt thereof.

(5). The amount of direction or guidance presented: While the specification is enabled for the treatment of hepatitis c virus using the prenylation inhibitor, cholesterol biosynthesis inhibitor, or inhibitor of HMG-CoA reductase, atorvastin, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of treating hepatitis c virus (infections) with any prenylation inhibitors, cholesterol biosythensis inhibitors, or inhibitors of HMG-CoA reductase. Nor is there any guidance provided as to a specific protocol to be

utilized in order to show the efficacy of all prenylation inhibitors, cholesterol biosythensis inhibitors, or inhibitors of HMG-CoA reductase in treating hepatitis c virus (infections).

(7). The quantity of experimentation necessary: The quantity of experimentation would be an undue burden to one of ordinary skill in the art and amount to the trial and error type of experimentation. Thus, factors such as "sufficient working examples," "the level of skill in the art" and "predictability" etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims.

In view of the breadth of the claims, unpredictability of treatment of hepatitis c virus (infections) using all prenylation inhibitors, cholesterol biosythensis inhibitors, or inhibitors of HMG-CoA reductase, and the lack of working examples regarding the activity as claimed, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention of claims 1-36.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-6, 8-10, 12-14, 16-18, 20-22, 24-26, 28-30, 32-34, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Prendergast et al. (WO 00/47196).

Prendergast et al. teaches a method of treating hepatitis C viral infections with at least one statin or statin-like compound. Further, the reference teaches the compound

disclosed may be administered alone or in combination with one or more other anti-viral drug. The components can be administered simultaneously, essentially simultaneously, or sequentially (page 16, lines 5-20), as recited in claims 1-2, 4-6, 8-10, 12-14, 16-18, 20-22, 24-26, 28-30,32-34, and 36.

The limitations of claims 5, 17, and 29, reciting the composition used in treating HCV infections is an intended use and receives no patentable weight in a composition claim.

The method and composition of claims 1-2, 4-6, 8-10, 12-14, 16-18, 20-22, 24-26, 28-30,32-34, and 36 are anticipated by Prendergast et al.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 7, 15, 19, 23, 27, 31, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prendergast et al. (WO 00/47196) in view of Gregg et al. (US Pat. No. 5,883,109).

Prendergast et al. is as discussed above.

Prendergast et al. fails to specifically teach the wherein said statin is atorvastatin or an analogue, derivative, variant or mimetic thereof.

Gregg et al. teaches inhibitors of HMG-CoA reductase include atorvastatin and cholesterol lowing drugs include atorvastatin (column 39, claims 15 and 18).

Gregg et al teach the equivalence of the various statins including pravastatin, simvastatin, and atorvastatin. To a person with ordinary skill in the art at the time the invention was made the substitution of any statin including atorvastatin is obvious because they are taught to be interchangeable in the prior art. The motivation to use atorvastatin is because the statin is taught to be an inhibitor of HMG-CoA reductase and cholesterol lowing drugs as are the other statins taught by Gregg et al. A skilled artisan would have reasonable expectation that the interchangeable use of any statin including atorvastatin will yield the same results of treating HCV.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on 8:30a.m.-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER